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EXAMINER	
HOLMES, REX R	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,858	SEIM ET AL.	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 36–60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 36, the phrase “coupled to memory” is inferentially included and vague. It is unclear if the memory is being positively recited or functionally recited. To positively claim element, it is suggested to first positively recite the element. Otherwise functional language such as “for” or “adapted to be” should be used. Additionally, the phrase “the control system disabling atrial ATP therapy” is likewise inferentially included and vague. It is unknown which element provides the atrial ATP therapy.

In claim 49, the phrase “a pace pulse” is inferentially included and vague. It is unclear what element is providing a pace pulse. It is suggested that the applicant include “a pace pulse generated by the energy delivery circuitry and delivered via …".

In claim 50, the phrase “a stimulus delivered” is inferentially included and vague. It is unclear what element is providing a stimulus. It is suggested that the applicant include “a stimulus generated by the energy delivery circuitry and delivered via …".

In claim 51, the phrase “after detection of an atrial arrhythmic event” is vague. It is unclear what element is providing detection of an atrial arrhythmic event. It is suggested that the Applicant include a sensing system for sensing internal cardiac

signals. It is noted that the control system measure impedance but fails to state that the control system further senses internal cardiac signals.

In claim 52, the phrase "after an atrial arrhythmic episode" is vague. It is unclear what element is providing an atrial arrhythmic episode. It is suggested that the Applicant include a sensing system for sensing internal cardiac signals. It is noted that the control system measure impedance but fails to state that the control system further senses internal cardiac signals.

In claim 53, the phrase "after detection of an atrial arrhythmic event" is vague. It is unclear what element is providing detection of an atrial arrhythmic event. It is suggested that the Applicant include a sensing system for sensing internal cardiac signals. It is noted that the control system measure impedance but fails to state that the control system further senses internal cardiac signals.

In claim 54, the phrase "after an atrial arrhythmic episode" is vague. It is unclear what element is providing an atrial arrhythmic episode. It is suggested that the Applicant include a sensing system for sensing internal cardiac signals (i.e. atrial arrhythmic episodes). It is noted that the control system measure impedance but fails to state that the control system further senses internal cardiac signals.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1–3, 9–20, 24–27, 31–39, 44–55 and 59–62 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al., U.S. Patent 7,031,773.

5. Regarding claims 1, 20, 36, 55, 61, and 62, (NOTE: Only the differing limitation of each claim will be indicated parenthetically; the common limitations will not be.) Levine et al. disclose measuring an impedance of an atrial lead (e.g., column 11, lines 5 and 7–10; column 13, lines 52–53; column 14, lines 21–23); comparing a measured impedance with an impedance threshold developed for a particular patient (e.g., column 11, lines 11–15; column 8, last line–column 9, lines 1–2; column 13, lines 59–60); disabling atrial ATP therapy delivery in response to a measured impedance deviating from an impedance threshold by a predetermined factor (e.g., column 11, lines 11–19 wherein the step of switching the electrode configuration to an electrode configuration other than the current electrode configuration represents disabling atrial ATP therapy delivery to the electrode configuration previously receiving the therapy); measuring a capture threshold (e.g., column 12, lines 26–28), and a sense amplitude (evoked response) (e.g., column 7, lines 59 and 65; column 10, lines 12–13 and 28–30) (claims 20, 55, and 62); comparing capture threshold, and sense amplitude measurements with capture threshold, and sense amplitude limits, respectively (e.g., column 10, lines 35–55) (claims 20, 55, and 62); an implantable housing (e.g., Fig. 1); detection circuitry (e.g., Fig. 2); energy delivery circuitry (e.g., Fig. 2); a lead system respectively coupled to a detection and energy delivery circuitry, a lead system comprising at least an atrial

lead (e.g., Figs. 1–2) and a control system provided in a housing and coupled to memory within which an impedance threshold developed for a particular patient is stored (e.g., Fig. 2) (claim 36).

6. Levine et al. disclose an impedance threshold is developed from a single atrial lead impedance measurement (claims 2, 26, and 37) and a plurality of atrial lead impedance measurements (claims 3, 27 and 38) (e.g., Fig. 3; column 11, lines 11–15); wherein measuring an impedance of an atrial lead comprises taking a plurality of impedance measurements to characterize an impedance of an atrial lead (claims 9 and 44) (e.g., Fig. 3, elements 208 and 220); measuring an impedance of an atrial lead comprises taking a single impedance measurement to characterize an impedance of an atrial lead (claims 10 and 45) (e.g., column 13, lines 52–53); a predetermined factor is characterized by a percentage change in a measured impedance relative to an impedance threshold (claims 11, 31 and 46) (e.g., column 11, lines 10–15) and a fixed delta change (500 ohms) in the measured impedance relative to the impedance threshold (claims 12, 32 and 47) (e.g., column 11, lines 13–14) and both a percentage change and a fixed delta change in the measured impedance relative to the impedance threshold (claims 13, 33 and 48) (e.g., column 11, lines 10–15 and 13–14); measuring an impedance comprises delivering a pace pulse via an atrial lead and deriving an impedance measurement using a delivered pace pulse (claims 14 and 49) (e.g., Fig. 3; column 12, lines 7–14) and using a delivered stimulus, a stimulus having an energy insufficient to effect atrial capture (claims 15 and 50) (e.g., Fig. 3; column 12, lines 22–30); an impedance is measured after detection of an atrial arrhythmic event and prior to

atrial ATP therapy delivery (claims 16, 34 and 51) (e.g., Fig. 3; column 12, lines 9–25); an impedance is measured after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery (claims 17, 35 and 52) (e.g., Fig. 3; column 12, lines 31–37); measuring an impedance comprises taking a plurality of impedance measurements after detection of an atrial arrhythmic event (claims 18 and 53) and after an atrial arrhythmic episode is declared (claims 19 and 54) and prior to atrial ATP therapy delivery (e.g., Fig. 3; column 12, lines 9–25); disabling ATP therapy delivery comprises, upon detection of an atrial arrhythmia, ignoring a capture threshold and sense amplitude deviations (claims 25 and 60), and disabling ATP therapy in response only to the measured impedance deviating from the impedance limit by the predetermined factor (claims 24, 25, 59, and 60) (e.g., Fig. 3; column 12, lines 31–37); an impedance threshold is capable of being characterized by a mean or a median of a plurality of atrial lead impedance measurements (claim 39) because a variance from a previous measurement by some other suitable value (e.g., as shown in column 12 lines 18–21), for example, a mean or median value, is commonly used in an impedance measurement system to measure lead impedance.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4–8, 21–23, 28–30, 40–43, and 56–58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al., U.S. Patent 7,031,773.

10. Levine et al. disclose the essential features of the claimed invention as discussed above except for an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements (claims 4 and 39) and by an atrial lead impedance measurement taken immediately before a currently measured impedance (claims 5, 28 and 40) and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement (claims 6, 29, and 41); and a predetermined amount of time is about one day (claims 7, 30 and 42) and more than one day (claims 8 and 42). However, it is well known in the art to characterize an impedance threshold as set forth in the claim limitations stated herein because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to have modified the invention of Levine et al. to include an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements and by an atrial lead impedance measurement taken immediately before a currently measured impedance and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement; and a predetermined amount of time is about one day and more than one day to provide the predictable results of a device that allows for delivery of optimal and efficient therapy in a timely manner.

11. Regarding claims 21–23 and 56–58, Levine et al. disclose the claimed invention as discussed in claims 20 and 24–25 above but does not disclose expressly detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the impedance, capture threshold, and sense amplitude as taught by Levine et al. (e.g., as discussed in the rejection for claims 20 and 24–25 above), to detect an ambiguity, because Applicant has not disclosed that detecting an ambiguity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the impedance, capture threshold, and sense amplitude as taught by Levine et al., because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time and provide a device that allows for delivery of optimal and efficient therapy in a timely

manner. Therefore, it would have been an obvious matter of engineering design choice to modify the impedance, capture threshold, and sense amplitude to obtain the invention as specified in the claims.

Response to Arguments

Applicant's arguments filed 5/22/08 have been fully considered but they are not persuasive. The Applicant argues that Levine fails to disclose disabling atrial anticachycardia pacing in response to a measured impedance because disabling therapy on one set of leads and then applying therapy elsewhere on another set of claims is not disabling therapy. The Examiner respectfully disagrees. Levine discloses disabling therapy on one set of leads in response to the measured impedance, and then enabling therapy on another set of leads once the therapy is disabled on the first set of leads. It is noted that the Applicants drafted their claims in a comprising format and thus do not preclude the enabling of therapy on a new set of leads right after the disabling of therapy.

The Applicant next argues that although Levine discloses that ATP therapy is one of the many therapies available in the system of Levine, the capture event that disables ATP therapy on one set of electrodes is not disabling ATP therapy delivery in response to the measured impedance. The Examiner respectfully disagrees. It is noted that the claims fail to call for the measuring and comparing of impedances to occur during ATP therapy. Levine discloses that it provides ATP therapy, checks for lead status, and then disables the therapy using the current lead setup if the impedance is

outside of a programmable impedance range. Therefore, Levine meets each and every limitation as set forth by the claims.

The Applicant next argues that predetermined and programmable impedance ranges disclosed in Levine are not developed for particular patients. The Examiner respectfully disagrees. As noted above Levine includes a programmable impedance range and further discloses that programmed parameters are stored and programmed using the microcontroller. It is further noted that Levine clearly shows that the programmable parameters are customized to suit the needs of the particular patient (e.g., column 11, lines 11–15; column 8, last line–column 9, lines 1–2; column 13, lines 59–60).

The Applicant next argues that Levine does not include a capture threshold limit and further that it is not inherent that the device has a capture threshold limit. In support of inherency the examiner cites Callaghan et al. (U.S. Pat. 4,969,467) and DeCote Jr. (U.S. Pat. 4,708,142). Both patents were cited as suitable capture methods in Levine as well as the basis for all modern capture techniques. Further capture limits are well known in the art to provide a minimum for the finding of capture and a maximum for limiting output power to a safe level, in the event of noise or due to increased heart rate due to exercise during the capture test.

Further Levine discloses that it determines if there is capture or not, thus it must include a capture limit otherwise it would not be able to determine if there is or is not capture.

The Applicant further argues that the claims rejected under 35 USC 103 are in error as they are dependent from allowable claims. As noted above, the independent claims are rejected and thus the dependent claims stand rejected.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The Examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762